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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,670	12/19/2005	Franco Macchi	207,380	5848
7590	10/11/2007			
Jay S Cinamon Abelman Frayne & Schwab 10th floor 666 Third Avenue New York, NY 10017			EXAMINER BLAND, LAYLA D	
			ART UNIT 1623	PAPER NUMBER
			MAIL DATE 10/11/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,670	Applicant(s) MACCHI, FRANCO	
	Examiner Layla Bland	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/19/2005, 5/3/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This application is a national stage entry of International Application No. PCT/EP04/51209, filed June 23, 2004. Claims 7-12 are pending in this application and are examined on the merits herein.

Claim Objections

Claim 10 objected to because of the following informalities: claim 10 is drawn to a method wherein hyaluronic acid is administered in the form of topical compositions containing sodium hyaluronate in concentrations between 0.01 and 10% by weight on the total weight of the composition. Composition and concentration should be either singular or plural, not both, and the word "on" should perhaps be "of." Appropriate correction is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of oral cavity aphthas, does not reasonably provide enablement for the prevention of such. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirements of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir., 1988). The court in *Wands* states, "Enablement is not precluded by the necessity for some experimentation, such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue', not 'experimentation'" (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations" (*Wands*, 8 USPQ2d 1404). Among these factors are: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

While all of these factors are considered, a sufficient amount for a *prima facie* case is discussed below.

(1) The nature of the invention and (2) the breadth of the claims:

The claims are drawn to a method for the prevention or treatment of oral cavity aphthas comprising administering hyaluronic acid. Stedman's Medical Dictionary 27th Edition defines "aphtha" as a small ulcer on a mucous membrane. Thus, the claims

taken together with the specification imply that the administration of hyaluronic acid can prevent ulcer formation on oral mucous membranes.

✓ *(3) The state of the prior art and (4) the predictability or unpredictability of the art:*

The Merck Manual Home Edition states that there are many types and causes of mouth sores. Any type of damage to the mouth, including poor-fitting dentures and jagged teeth, can cause ulcers to form in the mouth. Many foods can be irritating and cause an allergic reaction, causing mouth sores. Viruses are a common cause of mouth sores. Canker sores are a common type of mouth sore, and their cause is unknown.

Given the wide variety of factors which can cause mouth sores, many of which are unknown, one skilled in the art would not reasonably expect a single composition to prevent all such occurrences.

(6) The amount of direction or guidance presented and (7) the presence or absence of working examples:

The specification has provided guidance for the treatment of patients who have an current ulcer.

However, the specification does not provide guidance for the prevention of ulcer formation. Patients who did not have a current ulcer were asked to contact the clinic at the onset of their next ulcer.

(8) The quantity of experimentation necessary:

Considering the state of the art as discussed by the references above, particularly with regards to the many causes of mouth sores and the high unpredictability in the art as

evidenced therein, and the lack of guidance provided in the specification, one of ordinary skill in the art would be burdened with undue experimentation to practice the invention commensurate in the scope of the claims.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites the limitation "the method as claimed in claim 1." Claim 1 has been cancelled. There is insufficient antecedent basis for this limitation in the claim. Claims 9-12 are similarly dependent on claims which have been cancelled.

Claims 8-11 are drawn to methods comprising sodium hyaluronate and are dependent on claim 7, which recites hyaluronic acid. Sodium hyaluronate is not hyaluronic acid. There is insufficient antecedent basis for this limitation in the claim. Based on the examples given in the specification [pages 3 and 4], all of which use sodium hyaluronate, it appears that claim 7 is intended to encompass hyaluronic acid or salts thereof. For the purposes of examination, the claim will be interpreted as such.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Di Schiena (EP 0444492, April 9, 1991, PTO-1449 submitted May 3, 2007).

Di Schiena teaches a composition, prepared in Example 2, comprising 0.2% of sodium hyaluronate of average molecular weight 1,500,000. The composition was tested on 10 patients who suffered from gingivitis or had undergone periodontal surgery and had surgical wounds. Tests conducted with other compositions deriving from other examples [see pages 3 and 4 for other examples] gave comparable results. [page 5, lines 1-19]

In addition to sodium hyaluronate, the composition of Example 2 contained sodium carboxymethylcellulose, water, p-oxybenzoate and propyl p-oxybenzoate as preservatives, sorbitol, and peppermint as a flavor [page 3, lines 28-35]. None of these are considered “active” ingredients; sodium carboxymethylcellulose is used as a thickener, and sorbitol is used as an excipient [page 3, lines 10-14].

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Bland whose telephone number is (571) 272-9572. The examiner can normally be reached on M-R 8:00AM-5:00PM UST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Layla Bland
Patent Examiner
Art Unit 1623
October 3, 2007

Shaojia Anna Jiang


Supervisory Patent Examiner
Art Unit 1623
October 3, 2007